

Remarks

Claims have been amended to overcome the non-art rejections.

Bases for the amendments to the claims are as follows:

Claim	Basis
1	p. 11, ll. 23 – 31 and p. 15, ll. 19 – 22
2	p. 9, ll. 20- 21
5 & 6	Figures 10 – 12 and Examples provide basis for “diameter” being the point of comparison. See for example, Example 2, where the collapsed diameter is 1.3 mm and the expanded diameter is 4.5 mm (p. 22, ll. 8 – 9).
9	Obvious omission of word.
10	p. 16, ll. 1 – 2
14	Claim 1 and p. 11, ll. 24 – 25
15	Both “polyetherurethaneurea” and “polyesterurethaneurea” are well known in the art to be “block copolymers” by their very nature.
16	p. 12, ll. 5 – 9.
33	p. 18, ll. 25 – 28
35	p. 18, ll. 22 – 24

Oath/Declaration Defect

Applicants respectfully traverse the assertion that the oath/declaration is defective because it does not include a claim for domestic priority under 35 USC 119(e) to Prov. Application No. 60/271,770. 37 CFR 1.63 provides the requirements for an oath/declaration. The present oath/declaration meets all the “requirements.” There is no requirement that Applicants claim priority under 35 USC 119(e) in 37 CFR 1.63. The provisions for claiming benefit of the provisional application are provided in 37 CFR 1.78. Applicants have claimed the benefit of US Provisional Application 60/271,770, filed February 27, 2001, in the Background of Invention, p. 1, ll. 4 – 5 (Docket No. AD6799 US PRV 2001-02-27), and benefit was also claimed to Docket No. AD6799 US PRV 2001-02-27 on the Application Data Sheet in accord with 37 CFR 1.76.

Non-Art Rejections

Applicants request reconsideration of the 35 USC 112, second paragraph, rejections of Claims 1, 2, 5 –7, 9, 10, 14 – 16, and 33 in view of the above amendments and the following remarks.

Applicants traverse the 35 USC 112, second paragraph rejections of claims 14 – 16 based on the assertion that “spandex” is a trademark. Contrary to the incorrect indication in Cook that “spandex” is a trademark, spandex is in fact a generic term having a well-established definition in the fiber art. The Federal Trade Commission Fiber Rules define spandex fiber as “A manufactured fiber in which the fiber-forming substance is a long chain synthetic polymer composed of at least 85% of a segmented polyurethane.” (see attached copy of “Rules and Regulations Under the Textile Fiber Products Identification Act” §303.7(k), p. 7)

Furthermore, Applicants traverse the 35 USC 112, second paragraph, rejection of claim 15 based on “the segmented polyurethanes” point made. As defined (see above), spandex itself provides sufficient antecedent basis for “the segmented polyurethanes of the spandex fibers.”

With respect to the 35 USC 112, second paragraph, rejection of Claim 16, Applicants note that it is well known that elastomeric yarns can be covered or uncovered – see attached copy of “Rules and Regulations Under the Textile Fiber Products Identification Act” §303.1(n), p. 2), and that “hard yarns” is a well understood term in the art (see Zarioglu, col. 4, ll. 41 – 43, and attached U.S. Patent No. 3,940,917, col. 1, ll. 11 – 16). Applicants nevertheless are willing to drop the “hard yarn” limitation in favor of the broader claim language.

Restriction

The Claims in the Application as filed stand restricted to the following inventions:

- I. Claims 1 – 17 and 32 – 34.
- II. Claims 18 – 31 and 35.

Applicants confirm their election of the invention of Group I (made with traverse) for examination, respectfully requesting, however that Claim 35, as currently amended, be added to Group I. Claim 35 in its amended form is limited to a cover for a balloon catheter instead of a method of manufacture.

Applicants respectfully traverse this restriction requirement with respect to Claims 18 – 31. Claims 18 – 31 have been amended to make it

clear that they all pertain to a method for making the cover of Claim 1. Claims 18 – 31, as amended, now are clearly linked to Claim 1. Applicants maintain that the restriction requirement should be withdrawn and the Groups rejoined because the Groups are clearly linked, and any added search burden is reasonable.

Art Rejection - Obviousness

12. At present, Claims 1 – 9, 11 – 14, and 17 are rejected under 35 U.S.C. §103(a) as being unpatentable over Cook in view of Fowler et al. Reconsideration of this rejection is requested in view of the following remarks.

Applicants respectfully point out that Cook does not teach or suggest a balloon catheter “cover” as maintained in the office action. Instead, Cook pertains to a reinforcing fabric that is internal to the balloon structure. See col. 2, ll. 38 – 43, where the balloon structure is defined as (emphasis added):

Balloon 12 includes a three layer wall, the inner layer 22 being an elastic impervious urethane membrane ..., the middle layer 23 being a knitted fabric tube, and the outer layer 24 being an elastic impervious urethane membrane ...

The knitted fabric of Cook provides a “stop limit” for otherwise compliant balloons, beyond which the balloon cannot expand. In the description, the fabric is knit in such a way that the elastomeric (e.g., spandex, erroneously noted in Cook as a trademarked term) component of the knitting yarn retracts after fabrication, thereby causing the hard yarn component (e.g., Kevlar® or Dacron®) of the yarn to become “loopy” to accommodate the excess length (see col. 3, ll. 23 – 26). The yarn used to knit the fabric is comprised of parallel twisted plies or filaments wherein one ply is strong and inelastic (hard yarn) and the other is elastic (col. 3, ll. 10 – 17). Also, see attached U.S. Patent No. 3,940,917, which more clearly describes the “loopy” effect that Cook. The present invention has elastic yarn in the circumferential direction and hard yarn in the longitudinal direction, not parallel to each other.

Upon inflation of the balloon disclosed in Cook, the internal (middle) fabric layer of the three-layer balloon expands until the hard yarn is

extended to its full length. With the hard yarn fully extended, no further expansion can occur. (col. 3, ll. 27 – 37) “It is understood that the ratio of maximum to minimum diameter of balloon 12 is determined by how loosely middle layer 23 is originally knit” (col. 3, ll. 42 – 45).

The fabric of Cook is designed to not decrease in length as it expands in diameter. Instead, it is capable of increasing in length at the same time it expands in diameter because the elastomeric yarns are in both the circumferential and longitudinal direction (col. 3, ll. 51 – 55). The present invention is dimensionally stable in the longitudinal direction (no substantial shortening or lengthening of the cover during inflation or deflation).

The office action states that Cook fails to teach that the fabric structure is of interconnected circumferential and longitudinal yarns, and argues that Fowler et al. fills that void.

Applicants maintain that the combination is improper. There must be some suggestion in the art to combine the references. They cannot be combined simply based on 20/20 hindsight based on Applicants' disclosure. Applicants find no basis provided in the office action that would lead one skilled in the art of “catheters” to look to “fluid-dispensing containers” such as disclosed in Fowler et al. for modifying a compliant (elastic) “balloon catheter” to suggest “covers” that can be used for both compliant and non-compliant (folded, non-elastic) balloon catheters. Further, Cook requires that the elastomer and hard fibers be parallel to each other (col. 3, ll. 10 – 17), that the fabric be a loosely-knitted “loopy” structure (col. 3, ll. 23 – 45), and that the fabric be capable of expanding three-dimensionally (col. 3, ll. 51 – 53). Using the fabric of Fowler et al. would destroy all of these requirements – the elastomer and hard fibers would not be parallel to each other, the fabric would not be loosely knit or “loopy”, and the fabric would not be capable of expanding three-dimensionally. There simply cannot be any motivation, short of impermissible hindsight, to so destroy the teachings of the primary reference.

But, even if the combination were proper and Fowler et al. did fill the void of interconnection as suggested in the office action, the current invention taken as a whole is still not taught or suggested. Cook alone falls

well short (in more ways than the interconnection noted in office action) of teaching or suggesting all the limitations of the present invention. It does not teach a balloon cover. It does not teach longitudinal dimensional stability (to lengthening as well as shortening). It does not teach elastic circumferential fibers and less elastic longitudinal fibers. At the most, for example, a combination of Cook and Fowler et al. would still require that the fabric be the middle layer of a balloon structure. There simply is no suggestion of a "cover."

Thus, in view of the above, these obviousness rejections cannot stand as a matter of law, and Applicants respectfully request that they be withdrawn.

13. At present, Claim 10 is rejected under 35 U.S.C. §103(a) as being unpatentable over Cook in view of Fowler et al. and further in view of Chaikof et al. Reconsideration of this rejection is requested.

Applicants direct attention to the above discussion of Cook in view of Fowler et al. Chaikof et al. is used only for its teaching with respect to triaxial braiding. As such, it does not cure any of the other deficiencies left in light of Cook in view of Fowler et al. So, even if Chaikof et al. taken as a whole suggests triaxial braiding, the combination of references would still fall short of making the claimed invention as a whole obvious.

Chaikof et al., however, even falls short on the triaxial braid limitation. Chaikof et al. is primarily directed to a biaxial braided structure. While it does provide for the possibility of triaxial braids (col. 8, ll. 11 – 14), these are not preferred. Note that wires are contemplated by the invention (col. 8, ll. 14 – 19), and that the reinforcing warp strands "may only be used over a small portion of the device" (col. 8, ll. 19 – 20). Also, note that, if more than a small portion of the device has the reinforcing warp strands, "... the device's inherent ability to bend is lost. It is the inherent ability of the device to contract longitudinally that allows it to bend" (col. 8, ll. 20 – 22). This would teach away from a triaxial braid for the entire fabric structure as claimed.

Thus, this obviousness rejection cannot stand as a matter of law, and Applicants respectfully request that they be withdrawn.

14. At present, Claim 15 is rejected under 35 U.S.C. §103(a) as being unpatentable over Cook in view of Fowler et al. and further in view of Gilding et al. Reconsideration of this rejection is requested.

Applicants direct attention to the above discussion of Cook in view of Fowler et al. Gilding et al. is used only for its teaching with respect to the segmented polyurethane species claimed. As such, it does not cure any of the other deficiencies left in light of Cook in view of Fowler et al. So, even if Gilding et al. taken as a whole suggests the segmented polyurethanes of claim 15, the combination of references would still fall short of making the claimed invention as a whole obvious.

Thus, this obviousness rejection cannot stand as a matter of law, and Applicants respectfully request that they be withdrawn.

15. At present, Claim 16 is rejected under 35 U.S.C. §103(a) as being unpatentable over Cook in view of Fowler et al. and further in view of Gilding et al. and further in view of Zafiroglu. Reconsideration of this rejection is requested.

Applicants direct attention to the above discussion of Cook in view of Fowler et al. further in view of Gilding et al. Zafiroglu is used only for its teaching with respect to covering spandex yarn with a hard yarn. As such, it does not cure any of the other deficiencies left in light of Cook in view of Fowler et al. further in view of Gilding et al. So, even if Zafiroglu taken as a whole suggests the covered elastomers of Claim 16, the combination of references would still fall short of making the claimed invention as a whole obvious.

Thus, this obviousness rejection cannot stand as a matter of law, and Applicants respectfully request that they be withdrawn.

16. At present, Claims 32 – 34 are rejected under 35 U.S.C. §103(a) as being unpatentable over Cook in view of Fowler et al. and further in view of Killion et al. Reconsideration of this rejection is requested.

Applicants direct attention to the above discussion of Cook in view of Fowler et al. Killion et al. is used only for its teaching with respect to varying properties along the length of the sleeve (with respect to Claims 32 and 33) and varying shape (with respect to Claim 34). As such, it does not cure any of the other deficiencies left in light of Cook in view of Fowler et al. So, even if Killion et al. taken as a whole were held to suggest varying properties along the length of the sleeve as in Claims 32 and 33 or shape as in Claim 34 and amended Claim 35, the combination of references would still fall short of making the claimed invention as a whole obvious.

Thus, this obviousness rejection cannot stand as a matter of law, and Applicants respectfully request that they be withdrawn.

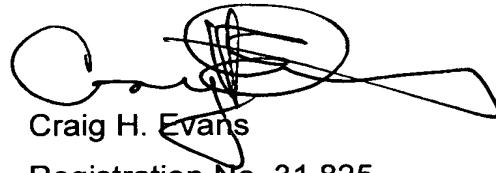
Information Disclosure Statement

Applicants submitted an Information Disclosure Statement dated November 15, 2002, and it was received by the Patent Office on November 18, 2002. Applicants respectfully request that the Examiner provide an initialed copy of PTO/SB/08A and PTO/SB/08B.

Conclusion

In view of the above remarks and amendments, it is felt that all claims are now in condition for allowance and such action is requested. Should the Examiner believe that an interview or other action in Applicants' behalf would expedite prosecution of the application, the Examiner is urged to contact Applicant's attorney by telephone at (302) 992-3219.

Respectfully submitted,



Craig H. Evans

Registration No. 31,825

Telephone: 302-992-3219

Facsimile: 302-992-3257

Dated: June 30, 2003